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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,550	02/09/2001	Akihiro Funakoshi	053466/0299	5276
22428	7590	05/24/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SPECTOR, LORRAINE	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/762,550	Applicant(s) FUNAKOSHI ET AL.	
	Examiner Lorraine Spector, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Part III: Detailed Office Action

Claims 14-26 are pending and under consideration.

The rejection of claims 14-24 and 26 under 35 U.S.C. §112, first paragraph is withdrawn in view of applicants amendments.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-14, 24 and 25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al., Surgical Forum 48:179, for reasons of record in the previous Office Action mailed 10/6/2003.

Applicants traversal in the response received 4/6/2004 has been fully considered but is not deemed persuasive. Applicants argue that PYY is not an IL-6 antagonist. This argument has been fully considered but is not deemed persuasive because an everyday definition of “antagonist” is “a chemical that acts within the body to reduce the physiological activity of another chemical substance” (www.m-w.com, accessed 5/21/2004). Accordingly, as PYY lowers levels of IL-6, it reduces the physiological activity of IL-6, and is an antagonist of such. Applicants arguments attempting to differentiate the effects of PYY on the pancreas as a whole from its specific effects on PYY have been fully considered but are not deemed persuasive. The person of ordinary skill in the art would be aware that the quotation made by applicants from Reed, that “peptide YY has multiple inhibitory actions on the proximal digestive tract, including inhibition of exocrine pancreatic secretion”, would mean that the effects of PYY are (a) not limited to the pancreas, and (b) occur through the usual channels of binding to receptors on cells and signaling to stimulate or inhibit certain cellular processes, including the production of exocrine proteins. It is noted that production of IL-6 is an exocrine function, as IL-6 is secreted from the cells that produce it. Therefore, inhibition of IL-6 production by the pancreas or other

nearby “proximal digestive tract” tissues would constitute inhibition of exocrine secretion, and as PYY is taught by Reed to lower circulating levels of IL-6, it is clearly an IL-6 antagonist. Thus, applicants attempt to distinguish “*direct* action” from reduction of IL-6 levels is inapposite. Further, there is no requirement in the claims that the antagonist bind directly to IL-6 or its receptor.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-23 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al., Surgical Forum 48:179-180, 1997, in view of Sato et al., Cancer Research 53(4):851-6, February 1993, and/or Kishimoto et al., EP 0 791 359 A1 for reasons of record in the previous Office Action mailed 10/6/2003.

Applicants argument of this rejection pertains to the Reed reference, and has been fully addressed above.

Claims 15- 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al., Cancer Research 53(4):851-6, February 1993, and/or Kishimoto et al., EP 0 791 359 A1, either or both references in view of Gross et al., Hepato-Gastroenterol. 40:522-530, cited by applicants, and Farkas et al., Neuroscience Letters 242(3):147-150. 2/20/98 for reasons of record in the previous Office Action mailed 10/6/2003.

This argument has been fully considered but is not deemed persuasive. Applicants argue that no motivation was cited to combine the references. This argument has been fully considered but is not deemed persuasive because the original rejection clearly states “Gross et al. teach that IL-6 concentrations are associated with acute pancreatitis; see page 525. Farkas et al. teach that experimental acute pancreatitis results in increased blood-brain barrier permeability (title), and that such is associated with increased IL-6 levels (page 149, paragraph bridging columns). Accordingly, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the compositions taught by Sato et al. or Kishimoto et al. to treat acute pancreatitis, in view of the teachings of Gross et al. and Farkas et al.” The motivation is found directly in the Gross and Farkas references.

Applicants further argue at page 8 of the response that because the actions of cytokines are pleiotrophic (many-faceted), that there would be no expectation of success at treating pancreatitis by inhibiting IL-6. This argument has been fully considered but is not deemed persuasive because it is contrary to current practice in the field of medicine. As evidenced by the primary references, Sato et al. and Kishimoto et al., and as stated in the statement of rejection, “Both references teach the use of anti-IL-6R antibodies for the treatment of IL-6 related conditions. ” Thus it is quite clear that the state of the art was that it was known to treat IL-6 related conditions by inhibiting the effects of IL-6. To suggest otherwise is contrary to the state of the art. Note also that the claims are to a “therapeutic method”, and do not require that the treatment “completely stop or prevent” pancreatitis, nor would claims to such complete cessation be found to distinguish over the art. *If* such occurs, it is an inherent feature of inhibiting IL-6, which is neither novel nor an unobvious treatment for acute pancreatitis.

Advisory Information:

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1647

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. **Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.**

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. **Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.**

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to **571-273-0893.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner